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| EXAMINER | |
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| HAGHIGHATIAN, MINA | |

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| 1616 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@panitchlaw.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/596,817 | CASTILE ET AL. | |
| | Examiner | Art Unit | |
| | Mina Haghighatian | 1616 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06/01/10*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-5,7-19 and 32-36* is/are pending in the application.

4a) Of the above claim(s) *32-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5 and 7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/07*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of claims*

Receipt is acknowledged of the preliminary amendments filed on 06/01/10. Claims 1, 3, 7-9, 16-19 and 32 have been amended and claims 2, 6 and 20-31 have been cancelled. No new claims have been added. Accordingly, claims 1, 3-5, 7-19 and 32-36 are pending.

### *Restriction*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-5 and 7-19, drawn to a composition for nasal delivery.

Group II, claim(s) 32, drawn to a method of administering.

Group III, claim(s) 33, drawn to a method of treating or preventing insomnia.

Group IV, claim(s) 34-35, drawn to a method of treating neurological disorder.

Group V, claim(s) 36, drawn to a nasal drug delivery device.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a "contribution" over the prior art and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The common technical feature in all groups is composition comprising zolpidem or a salt thereof in a solution formulation for nasal delivery. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Kramer et al (US 20040241100) discloses a composition comprising the claimed ingredients.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Alan Nadel on 06/01/2010 and as stated on Remarks filed with preliminary amendments of 06/01/10, a provisional election was made with traverse to prosecute the invention of Group I, claims **1, 3-5, 7-19**. Affirmation of this election must be made by applicant in replying to this Office action. Claims 32-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with

37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

time the application was filed, had possession of the claimed invention. Claim recites the concentration of zolpidem as "0.8 to 0.97 mg/ml". The upper limit of 0.97 is not disclosed in the specification and thus has no support. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 8, 16 and 17 are indefinite for reciting a range that is broader in scope than the independent claim 1. The recited range is the concentration of zolpidem which is 24 to 80 mg/ml for claim 7; 2.4 to 16 mg/ml for claim 8; 30 to 60 mg/ml for claim 16 and from 3 to 20 mg/ml for claim 17. All said ranges are outside of the range disclosed in the independent claim 1 (0.8 to 0.97 mg/ml).

NOTE: it is assumed that the recited upper limit of 0.97 mg/ml is a typographical error and should be 97 mg/ml. For the examination purposes, claim 1 would be interpreted as having a range of 0.8 to 97 mg/ml.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before

the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 3-5, 7-9, 13-14, 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kramer et al (US 20040241100).**

Kramer et al teach a pharmaceutical composition for nasal administration, which includes **zolpidem**, a pharmaceutically acceptable salt thereof, or a combination thereof, and a pharmaceutically acceptable nasal carrier in liquid form. Another embodiment of the present invention provides a method for inducing sleep, which includes nasally administering to a subject in need thereof a pharmaceutical composition, which includes zolpidem, a pharmaceutically acceptable salt thereof, or a combination thereof, and a pharmaceutically acceptable nasal carrier in liquid form (see abstract).

Kramer et al disclose advantages of nasal administration of a formulation comprising zolpidem in liquid form. Such advantages include efficient and ease of use, reduced need for supervision of administration, minimized or bypassed first pass metabolism and a beneficial pharmacokinetic profile (see [0014] to [0017]).

The suitable dosage is stated as from 0.001 to 250 mg zolpidem in a carrier in an amount of from 0.002 to 4 ml. This provides a teaching of from 0.5 to 62.5 mg/ml concentration (see [0023]-[0026]).

The compositions may be in a solution form and the carrier may be one or more of water, saline solution, ethanol, polyethylene glycol, propylene glycol etc

(see [0035]). Other components that may be added include mucoadhesives such as **chitosan** hydroxycellulose (see 0036]). Suitable salt for the active agent include tartaric acid and tartrate (see [0040] and [0041]). The formulations also comprise a buffer such that the composition has a **pH** of from 3 to 10, or any value in between (see [0038]).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 10, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al (US 20040241100) as applied to claim 1 above, and in view of Auh et al (EP 1250925).**

Kramer et al teach a pharmaceutical composition for nasal administration, which includes **zolpidem**, a pharmaceutically acceptable salt thereof, or a combination thereof, and a pharmaceutically acceptable nasal carrier in liquid form. Another embodiment of the present invention provides a method for inducing sleep, which includes nasally administering to a subject in need thereof a pharmaceutical composition, which includes zolpidem, a pharmaceutically acceptable salt thereof, or a combination thereof, and a pharmaceutically acceptable nasal carrier in liquid form (see abstract).

Kramer et al disclose advantages of nasal administration of a formulation comprising zolpidem in liquid form. Such advantages include efficient and ease of use, reduced need for supervision of administration, minimized or bypassed first pass metabolism and a beneficial pharmacokinetic profile (see [0014] to [0017]).

The suitable dosage is stated as from 0.001 to 250 mg zolpidem in a carrier in an amount of from 0.002 to 4 ml. This provides a teaching of from 0.5 to 62.5 mg/ml concentration (see [0023]-[0026]).

The compositions may be in a solution form and the carrier may be one or more of water, saline solution, ethanol, polyethylene glycol, propylene glycol etc (see [0035]). Other components that may be added include mucoadhesives such as **chitosan** hydroxycellulose (see 0036]). Suitable salt for the active agent include tartaric acid and tartrate (see [0040] and [0041]). The formulations also comprise a buffer such that the composition has a **pH** of from 3 to 10, or any value in between (see [0038]).

Kramer et al lacks specific disclosure on addition of cyclodextrines. This deficiency is cured by Auh et al.

Auh et al teach nasal spray formulations comprising ondansetron hydrochloride as the active agent and other components such as solubuilizer including sulfobutyl ether β–cyclodextrin sodium salt (see abstract). It is disclosed that the soulbilizers used such as SBCD, DMCD, 2HPβCD are present in an amount between 7 and 20% by weight based on the weight of the formulation (see [0019]). The pH of the formulations is preferably adjusted to a week acidity of 4 to 6 (see [0021]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have implemented the teachings of Auh et al in the

formulations of Kramer et al because it is disclosed that cyclodextrins are suitable solubilizers for nasal formulations. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Furthermore, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

**Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al (US 20040241100) in view of Auh et al (EP 1250925) as applied to claim 1 above, and in further view of Birch et al (WO 03080021).**

Kramer and Auh et al have been discussed above. Their combination lacks disclosure on the chitosan salt being chitosan glutamate or the amount of chitosan added. These deficiencies are cured by Birch et al.

Birch et al teach aqueous formulations suitable for intranasal administration comprising buprenorphine and a pectin or chitosan. Such formulations can induce rapid and prolonged analgesia when delivered intranasally to a patient (see abstract). An aqueous solution formulation for

intranasal administration comprises a) from 0.1 to 10 mg/ml of buprenorphine, b) from 0.1 to 20 mg/ml of a **chitosan** and c) from 0.1 to 15 mg/ml of HPMC. The solution has a pH of from 3 to 4.8 (see page 3, embodiment 2).

Birch et al also disclose that preferred salts of chitosan are glutamate and chloride (see page 12, lines 1-5 and 21-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of nasal formulations comprising an active agent such as zolpidem, cyclodextrin derivative and a chitosan as taught by Kramer and Auh et al, to have looked in the art for the specific and suitable salts of chitosan and amounts of it for nasal formulations as disclosed by Birch et al with the reasonable expectation of preparing efficient, stable and suitable formulations for nasal administration. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Furthermore, the claims would have been obvious because the technique for improving a particular formulation was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

**Claims 1, 3-5 and 7-10, 13-15, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birch et al (WO 03080021) in view of Liu et al (WO 03095498, in Japanese provided by Applicants) (as evidenced by its US equivalent document US 20050215520).**

Birch et al teach aqueous formulations suitable for intranasal administration comprising buprenorphine and a pectin or chitosan. Such formulations can induce rapid and prolonged analgesia when delivered intranasally to a patient (see abstract). An aqueous solution formulation for intranasal administration comprises a) from 0.1 to 10 mg/ml of buprenorphine, b) from 0.1 to 20 mg/ml of a **chitosan** and c) from 0.1 to 15 mg/ml of HPMC. The solution has a pH of from 3 to 4.8 (see page 3, embodiment 2).

Birch et al also disclose that preferred salts of chitosan are glutamate and chloride (see page 12, lines 1-5 and 21-24). The formulations may also comprise an absorption promoting agent including chitosans, surface active agents, cyclodextrins, etc (see page 19, lines 16-20).

Birch et al lacks specific disclosure on the active agent being zolpidem and the derivatives of cyclodextrin. These deficiencies are cured by Liu et al.

Liu et al teach a sterile water-soluble complex of water-insoluble or sparingly-soluble organic medicines and beta-cyclodextrin derivatives. A fully-water-soluble complex can be prepared from any water-insoluble or sparingly-soluble organic medicines or other organic compounds (see abstract). One

suitable active agent for the said drug-cyclodextrin complex formulation is **zolpidem** (see Table 1). Example 2 also discloses a formulation comprising zolpidem and a cyclodextrin derivative.

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Birch et al on nasal formulations to have looked in the art for other active agents and cyclodextrin derivatives suitable for the said nasal formulations with the reasonable expectation of success in broadening the scope of the disclosed nasal formulations to other active agents for treating other disorders with the same rapid absorption, efficient and easy to administer delivery systems. In other words, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The motivation for substituting them flows from their having been used in the prior art, and from their being recognized in the prior art as useful for the similar purpose. As shown by the recited teachings, instant claims are no more than the substitution of conventional components of active agents. It therefore follows that the instant claims define prima facie obvious subject matter. Cf. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

**Claims 1, 3-5 and 7-15, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loftsson et al (US 6,699,849) in view of Kramer et al (US 20040241100).**

Loftsson et al teach methods for enhancing the complexation efficiency of a drug with cyclodextrin and for enhancing the availability of a drug following administration of a cyclodextrin-drug complex (see abstract). It is disclosed that in aqueous solutions, cyclodextrins form complexes with many drugs through a process in which the water molecules located in the central cavity are replaced by either the whole drug molecule or more frequently by some lipophilic portion of the drug structure (see col. 2, lines 1-6). It is further disclosed that cyclodextrins act as penetration enhancers by increasing drug availability at the surface of the biological barrier (see col. 4, lines 6-8).

Loftsson et al teach that particularly preferred cyclodextrins for use in the said methods and formulations include β–cyclodextrin sulfobutyl ether and hydroxypropyl-β-cyclodextrin, etc (col. 7, lines 4-5 and 56-60). Various active agents such as benzodiazepines have been listed as suitable for the said drug-cyclodextrin complexes (see columns 9 to 11). The said formulations are suitable as nasal sprays and the pH is maintained at levels of below 5 (see col. 10, lines 12-40) and col. 11, lines 42-55). In Example 8, the bioavailability of midazolam and sulfobutylether β-cyclodextrin is shown.

Loftsson et al lack specific disclosure on the addition of chitosan and the active agent being zolpidem. These deficiencies are cured by Kramer et al.

Kramer et al, discussed above teach nasal formulations comprising zolpidem or a salt thereof such as tartrate and chitosan.

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Loftsson et al on nasal formulations to have looked in the art for other active agents and other additives such as chitosan suitable for the said nasal formulations with the reasonable expectation of success in broadening the scope of the disclosed nasal formulations to other active agents for treating other disorders with the same rapid absorption, efficient and easy to administer delivery systems. In other words, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. The motivation for substituting them flows from their having been used in the prior art, and from their being recognized in the prior art as useful for the similar purpose. As shown by the recited teachings, instant claims are no more than the substitution of conventional components of active agents. It therefore follows that the instant claims define prima facie obvious subject matter. Cf. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616